

subpoenas, SICOR produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that SICOR has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

- 149. In addition to marketing the spread, SICOR utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, such as free goods, SICOR provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.
- 150. As set forth above, SICOR's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by the State. The acts of SICOR in reporting false and misleading price information used by Medi-Cal in setting reimbursement amounts:
- (a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified SICOR drugs in amounts that substantially exceeded the amounts that should have been paid according to law.
- (b) Were knowingly committed in order to induce SICOR's customers, and those acting in concert with them, to select SICOR's drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- 151. The actions by SICOR alleged herein were a substantial factor in causing the damages that California has sustained as set forth below.

# P. SPECIFIC ALLEGATIONS AS TO DEFENDANT SMITHKLINE

152. From on or after January 1, 1994, to the present, SMITHKLINE DEFENDANTS knowingly caused over ten thousand false claims for reimbursement for SMITHKLINE DEFENDANTS' drug products described herein to be presented to the Medi-Cal program for payment or approval. SMITHKLINE DEFENDANTS knowingly used or caused the use of false



statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendants' drugs including those specified in this Section and in Exhibit R, attached herein. This Exhibit lists the drug products' NDC; label name; date; AWPs from FDB; CDP; a market price per unit; and the source of that market price. The wrongful acts committed by SMITHKLINE DEFENDANTS included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendants' drugs, and which would cause the claims for such reimbursements to be false. In connection with reporting a false inflated AWP of \$166.00 for SMITHKLINE's drug Kytril, SMITHKLINE implemented a plan to offer deep discounts to the oncology supply houses which supplied Kytril to physicians and clinics. On or about February 9, 1994, SMITHKLINE employee Elizabeth Posner sent an internal memorandum to Howard Pien regarding the WAC prices for Kytril. The memorandum recommended that SMITHKLINE provide Kytril to the oncology supply houses (such as Florida Infusion, OTN, or Oncology Supply) at a 16 2/3% discount off WAC or free goods equivalent in order to create a profit incentive. In fact, SMITHKLINE did create a standard discount to all oncology supply houses based on profit received from Medicare and Medicaid reimbursement.

153. In a power point presentation on or about February 28, 1994, prior to the launch of the Kytril 1mg vial by SMITHKLINE, the "Price Strategy" for the Kytril launch was "AWP is high enough to provide an attractive reimbursement margin for customers" and "Moderate list price advantage disguises true customer acquisition cost advantage." SMITHKLINE employees created numerous comparisons of reimbursement of SMITHKLINE's Kytril and GLAXO's Zofran and distributed them to induce the physicians to purchase Kytril over Zofran, based on the profit or kickback they would receive in the form of higher reimbursement from Medicare and Medicaid funds. For example, a SMITHKLINE drug salesman named Heidi Haas ("HAAS") gave a health care provider in the Denville, New Jersey area promotional literature entitled "Cost v. Profit" between March 11, 1994, and February 6, 1995. SMITHKLINE's handout advocated that the physician use two SMITHKLINE 1 mg vials of Kytril on three patients and bill Medicare for three vials of Kytril. SMITHKLINE's handout further showed



that the profit received by prescribing physicians for use of its drug Kytril on three patients was \$163.20 and the profit received if its competitor GLAXO's Zofran was used was \$108.00. HAAS also distributed handouts with a detailed analysis of how its physician customers should pool vials of Kytril to obtain the most profit. On or about March 18, 1994, Horace Cook, Director of Trade Operations at SMITHKLINE, represented to Medical Economics Data (Red Book) employee, Lynne Handler ("HANDLER"), a false inflated AWP for SMITHKLINE's drug Kytril of \$166.00, when Kytril's true price to SMITHKLINE's customers was approximately \$112.75, as stated in Florida Infusion's catalog (an insider publication not available to the Government). COOK obtained HANDLER's signature on a document reporting the AWP for Kytril of \$166.00 and distributed the document to various persons including, but not limited to, health care providers making claims under Medicare Part B and various States' Medicaid programs.

- 154. In a chart created by SMITHKLINE for Kytril oncology supply house margins for April of 1994, the oncology supply house cost was 12% lower than WAC, creating a profit margin of 29.6% from Medicare reimbursement. The "Margin" was calculated on the chart by dividing the difference between AWP and Cost by AWP.
- 155. During that same time period, SMITHKLINE also offered a "special 8% added discount" which increased the profit received from Medicare to 35.2%.
- 156. On or about April 15, 1994, Peg Skelly ("SKELLY"), a SMITHKLINE employee, sent a letter to Jenie DeKneff, an official of the Texas Department of Health, wherein SKELLY represented for purposes of Texas Medicaid vendor reimbursement a false inflated AWP for Kytril, of \$166.00 when the price actually charged to SMITHKLINE's customers was \$112.75.
- 157. Another example of SMITHKLINE promoting the pooling of vials is, on or about October 17, 1994, Tom McClean, an employee of SMITHKLINE, prepared a memo entitled "Kytril Profit Model" and distributed it to other SMITHKLINE employees. The memo was also distributed to at least one health care provider in the Brunswick, Georgia area between October 17, 1994 and February 6, 1995. The memo compared the Medicare and Medicaid reimbursement for Kytril and Zofran, promoted pooling the 1mg single dose vials of Kytril, and



set out a format to market Kytril based upon the spread, the amount of the kickback SMITHKLINE caused to be paid from Government funds to SMITHKLINE's customers, the health care providers. The memo stated that, when using .7mg of 1 mg vial of Kytril, the average dose when pooling vials, the physician received \$81.00 of profit, because the AWP for a 1 mg vial of Kytril was \$166.00 and the actual cost of Kytril when pooling 1 mg vials was an average of \$85.00. McClean's claim, that costs go down and, therefore, profits to SMITHKLINE's customers go up as a result of pooling, was only true if the physician billed Medicare for full 1 mg vials when only .7 mg of 1 mg vials were used. For example, using two 1 mg vials for three patients and billing Medicare for three full 1 mg vials.

158. In a memorandum regarding the Zofran "price increase" dated January 11, 1995, from SMITHKLINE employee Dick Van Thiel ("Van Thiel") to SMITHKLINE employees Jerry Karabelas and Howard Pien, SMITHKLINE's Van Thiel reported, "I believe Glaxo is trying to provide oncology supply houses the same margins SB offers." VAN THIEL further stated that GLAXO raised its "price" or AWP, but offered a 14% rebate to all non-hospital customers, therefore providing a profit of \$52.75 per 32mg dose and a 28% margin to the doctor, whereas Kytril provided a profit of \$49.40 per 1mg dose and a 30% profit margin to the doctor. As a result, VAN THIEL concluded:

This new Glaxo strategy allows an oncologist to make more money by using Zofran due to higher price but allows a lesser margin than Kytril by 2%.

I believe the Zofran price increase and across the board discount for oncology supply houses that match our margins is a clear signal that Glaxo does not want to compete on price but is willing to lower price to meet our margins with oncology supply houses.

- 159. A SMITHKLINE memorandum dated February 25, 1995, showed that, after GLAXO increased the AWP of Zofran, the profit per vial was \$66.03, whereas the profit per vial for Kytril was \$47.05. However, SMITHKLINE's analysis further calculated the profit per dose. The profit per dose of Zofran was \$52.82 and the profit per dose of Kytril was \$70.84. The calculation of profit per dose was based on a dose of .8 mg with 1 mg full vial reimbursed, while the remainder of the vial was to be "pooled" by the physician.
  - 160. In an email dated March 25, 1995, from SMITHKLINE employee William



Chrencik to SMITHKLINE employee Robert Turner regarding the importance of reimbursement factors in the clinic setting, Chrencik concluded:

- 1. If an oncologist uses Kytril he makes money.
- 2. However, if an oncologist uses Zofran he loses money.

  Therefore, there is a positive profit impact to the clinic when Kytril is utilized.
- 161. SMITHKLINE knew that the prices it reported to Red Book, First Data Bank, the Texas Department of Health, and others were used to set Medicare and Medicaid reimbursement. In an internal report entitled "Kytril Market Situation Analysis" created on or about May 17, 1995, a SMITHKLINE employee stated:

Medicare currently reimburses physicians the average wholesaler price (AWP) for chemotherapeutic agents administered in the office or clinic. Because AWP is set by the manufacturer and often does not reflect actual market prices (wholesaler prices are normally much lower), profit-seeking physicians have a strong incentive to use whichever agents offer the greatest spread between actual cost and AWP.

162. SMITHKLINE created computer software programs based on the concept that a physician can "make money" if he uses Kytril and will "lose money" if he uses Zofran and distributed the programs to its sales personnel for use in physicians' offices. SMITHKLINE designed the programs "to calculate total profits that can be achieved by using Kytril instead of Zofran." The program calculated the "Differences in Reimbursement" between Kytril and Zofran, the "Total Reimbursement" per day and per year, the cost per day and per year, and the "Difference By Switching to Kytril Per Year." Furthermore, the program was able to calculate "profit" based on the percentage of Medicare and/or Medicaid patients the physician treated. SMITHKLINE entered into rebate agreements with physicians groups such as PRN which provided for payments of kickbacks. On or about October 16, 1995, David Lichtenstein, Senior Contract Manager, and Jerry Ghastin, Account Manager, both employees of SMITHKLINE, offered to Bob Whren, Executive Vice President of Physicians Reliance Network ("PRN") to pay a rebate of \$11.60 per vial of SMITHKLINE's Kytril purchased in exchange for the condition that PRN maintain and market Kytril as the preferred oral and injectable anti-emetic. Bob Whren on behalf of PRN accepted SMITHKLINE's offer and SMITHKLINE's financial incentives on October 25, 1995, and SMITHKLINE's David Lichtenstein and Jerry Ghastin also



signed the SMITHKLINE/PRN letter agreement on October 31, 1995. On or about April 4, 1996, SMITHKLINE's Jerry Ghastin prepared a utilization report for PRN, comparing PRN's utilization of SMITHKLINE's Kytril, versus its competitor GLAXO's Zofran. The report showed that SMITHKLINE's financial inducements dramatically increased utilization of SMITHKLINE's Kytril and at that time Kytril had 82.14% of the patient market share.

- 163. Although the true price of SMITHKLINE's drug Kytril was decreasing in the market place, as evidenced by SMITHKLINE's increase of the rebate paid to its customers who prescribed Kytril and the guaranteed price of \$102.00, SMITHKLINE represented to the Government that the price for Kytril was increasing, by reporting a false inflated AWP of \$173.95 on or about March of 1996.
- 164. Van Thiel and other SMITHKLINE employees strategized, analyzed, and implemented the fraud scheme to provide larger and larger kickbacks to the physicians to induce more sales of Kytril. In response to GLAXO's false inflation of Zofran's AWP to \$244.43 on March 7, 1996, SMITHKLINE reported a new false inflated AWP for Kytril of \$173.95 on or about March 26, 1996.
- 165. Van Thiel and SMITHKLINE employee Rich Francovitch analyzed the AWP increases in a power point presentation on or about June 6, 1996. The power point presentation showed calculations of "profit" for both Kytril and Zofran as a result of the increases. The power point also shows that the "profit" or kickback was being paid for by Medicare funds. SMITHKLINE actively encouraged physicians to dose Kytril based upon weight and then to pool the vials of Kytril to receive greater reimbursement. In a report entitled "Kytril Situation Analysis 1996," under the heading "Opportunities/Threats" a SMITHKLINE employee stated:

Physicians are not taking advantage of *Kytril's* full economic benefit because a large percentage of them are still giving an entire 1mg vial to each patient rather than dosing based on weight. SB is encouraging weight-based dosing - a move that could save customers 20-30%, and offset the effects of Zofran down-dosing. By lowering *Kytril's* effective cost per dose, SB expects to increase total usage, offsetting the 20%-30% reduction in dose. . . .

166. In a letter agreement dated on or about June 26, 1996, SMITHKLINE's David Lichtenstein and Jerry Ghastin offered to amend the SMITHKLINE/PRN Kytril Agreement



dated October 16, 1995 effective July 1, 1996, by increasing PRN's rebate to \$20.46 per vial and guaranteeing a net price of \$102.00 for SMITHKLINE's drug Kytril. The terms of the agreement were accepted by PRN's Bob Whren on July 8, 1996. PRN received rebates from SMITHKLINE for the third quarter of 1996 totaling \$235,658.28 and for the fourth quarter of 1996 totaling \$276,946.56.

- 167. The SMITHKLINE prepared a document entitled "ORAL ANTI-EMETICS COVERAGE EFFECTIVE 1/1/98" showing the difference in reimbursements when using its drug, Kytril, as compared to its competitor's drug, Zofran. SMITHKLINE's calculations for both drugs were based on each drug's AWP. SMITHKLINE concluded, "All parties, the payer, patient and the physician are better off using Kytril Tablets."
- 168. The acts of the SMITHKLINE DEFENDANTS in reporting false and misleading price information, used by Medi-Cal in setting reimbursement amounts:
- (a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified SMITHKLINE DEFENDANTS' drugs in amounts that substantially exceeded the amounts that otherwise should have been paid according to law.
- (b) Were knowingly committed in order to induce the SMITHKLINE DEFENDANTS' customers, and those acting in concert with them, to select the SMITHKLINE DEFENDANTS' drugs for Medi-Cal recipients, rather than select similar drugs of competitors, or prescribe alternative therapies.
- 169. The actions by the SMITHKLINE DEFENDANTS were a substantial factor in causing the damages that California has sustained as set forth below.

# Q. <u>SPECIFIC ALLEGATIONS AS TO DEFENDANT WARRICK</u>

170. From on or after January 1, 1994, to the present, Defendant WARRICK knowingly caused over four million false claims for reimbursement for WARRICK's drug products described herein to be presented to the Medi-Cal program for payment or approval. Defendant WARRICK knowingly used or caused the use of false statements about the prices of its drug products resulting in Medi-Cal paying grossly excessive, unreasonable and unlawful amounts for Defendant's drugs, including those specified in this Section and in **Exhibit K** attached herein. This Exhibit lists the drug products' NDC; label name; date; AWPs from FDB;



CDP; a market price per unit; and the source of that market price. The wrongful acts committed by WARRICK included, but were not limited to, knowingly making false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendant's drugs, and which would cause the claims for such reimbursements to be false. WARRICK has reported and continues to report an inflated AWP and WAC which in turn affect Federal Upper Limit prices and cause over-reimbursement of their drugs California. WARRICK has taken the position in this litigation that they initially reported an AWP at ten to twenty percent below the equivalent brand product's AWP, and that AWP remained constant over time. With respect to WARRICK's drugs, however, there has been a decline in real wholesale prices as the generic drugs remain on the market over time. This decline in price has not been passed on to the consumer or to California by WARRICK.

- 171. One of WARRICK's customers asked WARRICK if they could be released from contractual obligations to deal with invoices containing arbitrary, artificially inflated and false price information which served no legitimate business purpose and which caused unnecessary, costly and meaningless bookkeeping and accounting work to be done. Instead, the customer asked to receive invoices in the future which more accurately represented the actual transactions reflected by the respective invoices.
- 172. WARRICK had significant spreads on its drugs, for example the Albuterol Inhaler (NDC 59930156001). In comparing wholesale prices of the inhaler in second quarter 2001 to the price reimbursed by DHS, up to 71% of the DHS price paid for the inhaler is spread. In other words DHS' price paid to the provider for the WARRICK inhaler is 351% of the contract price paid by providers.
- 173. SCHERING-PLOUGH CORP. (WARRICK's parent company) attempted to gain market share by increasing the spread between reported price and actual price for its drugs. Parent company SCHERING-PLOUGH CORP. has admitted that its goal is to increase utilization and expand sales. SCHERING-PLOUGH CORP. and WARRICK were motivated to dominate the generic market through pricing flexibility in marketing new generic drugs. SCHERING-PLOUGH CORP. has admitted that it could reduce fraud by lowering the AWP on their products.



- 174. The Defendants WARRICK and SCHERING-PLOUGH CORP. entered into specific agreements and contracts with one or more telemarketing companies, including TMS (a/k/a Access Worldwide) a company located in Florida, but doing business by making telephonic contacts in California. As part of telephone sales pitches, telemarketers would advertise and promote WARRICK and SCHERING-PLOUGH CORP. products in part by marketing the spread and urging purchases of these products based upon the large and profitable spread between the net price the pharmacies would pay for the drugs and the high reimbursement amount those pharmacies would receive, known as the "profit message" and/or Return on Investment ("ROI"), among other phrases.
- 175. The acts of Defendant WARRICK in reporting false and misleading price information used by Medi-Cal in setting reimbursement amounts:
- (a) Were knowingly committed in order to cause Medi-Cal to pay claims for the specified WARRICK drugs in amounts that substantially exceeded the amounts that should have been paid according to law.
- (b) Were knowingly committed in order to induce Defendant WARRICK's customers, and those acting in concert with them, to select Defendant WARRICK's drugs for Medi-Cal recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- 176. The actions by Defendant WARRICK were a substantial factor in causing the damages that California has sustained as set forth below.

#### VII.

# **CALIFORNIA LAW VIOLATED BY DEFENDANTS**

- 177. At all times relevant and material to this action, each Defendant "knew" or acted "knowingly," which terms are defined in California Government Code section 12650, subdivision (b)(2), in causing the making, presenting, or submission of false claims. In that respect, each Defendant acted:
  - (a) With actual knowledge of the information; or
  - (b) In deliberate ignorance of the truth or falsity of the information; or
  - (c) With reckless disregard of the truth or falsity of the information.



- 178. At all times relevant and material to this action, each Defendant "caused" the making, presenting, or submitting of false claims, as that term is defined in California Government Code section 12651, in causing:
- (a) The presentation of false claims for payment or approval by Medi-Cal; and,
- (b) The making and using of false statements and/or records for the purpose of getting false claims approved or paid by Medi-Cal. At all times relevant and material hereto, each Defendant knew that its conduct would cause Medi-Cal to pay claims for the specified prescription drugs in amounts exceeding that contemplated by applicable law.
- 179. Each Defendant "knowingly" reported or caused to be reported false and inflated AWPs, DPs, and WACs to FDB, Red Book, and the other pricing services by systematically concealing or otherwise failing to report decreases in the prices of the specified prescription drugs.
- 180. At all times relevant and material hereto, each Defendant knew that its conduct was in violation of California Welfare and Institutions Code section 14107.2, which prohibits receiving remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind in return for the purchasing, ordering, or arranging for or recommending the purchasing, or ordering of any goods, service or merchandise for which payment may be made, in whole or in part, under the Medi-Cal Program.

#### VIII.

## **CAUSES OF ACTION AND DAMAGES**

## FIRST CAUSE OF ACTION

# CALIFORNIA FALSE CLAIMS ACT, CAUSING PRESENTATION OF FALSE CLAIMS TO CALIFORNIA

California Government Code section 12651, subdivision (a)(1)

- 181. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.
  - 182. At all times relevant and material to this First Amended Complaint in



Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] caused false claims for payment or approval, in the form of false Medi-Cal Cost information for the drugs specified herein to be presented to officers or employees of the State. As a result, the State paid out as reimbursement to the Medi-Cal providers of the specified prescription drugs sums of money grossly in excess of the amounts contemplated by law, resulting in great financial loss to the State.

183. Defendants' conduct violated Government Code section 12651, subdivision (a)(1) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

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## SECOND CAUSE OF ACTION

# CALIFORNIA FALSE CLAIMS ACT, CAUSING FALSE RECORDS OR STATEMENTS TO BE MADE OR USED TO GET FALSE CLAIMS PAID OR APPROVED BY CALIFORNIA

California Government Code section 12651, subdivision (a)(2)

- 184. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.
- At all times relevant to this First Amended Complaint in Intervention, Defendants 185. ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] caused false records or statements to be made or used to get false claims to be paid or approved by the State, in that Defendants caused false records or statements of the Medi-Cal Cost of Defendants' specified prescription drugs to be used by the State to pay or approve claims presented by the providers and suppliers of Defendants' specified prescription drugs. These paid or approved claims were



grossly in excess of the amounts contemplated by law, resulting in great financial loss to the State.

186. Defendants' conduct violated Government Code section 12651, subdivision (a)(2) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

# THIRD CAUSE OF ACTION

CALIFORNIA FALSE CLAIMS ACT, BENEFICIARIES OF INADVERTENT SUBMISSIONS OF FALSE CLAIMS TO CALIFORNIA, SUBSEQUENTLY DISCOVER THE FALSITY OF THE CLAIMS, AND FAIL TO DISCLOSE THE FALSE CLAIMS TO CALIFORNIA WITHIN REASONABLE TIME AFTER DISCOVERY OF THE FALSE CLAIMS

# California Government Code section 12651, subdivision (a)(8)

- 187. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.
- 188. At all times relevant to this First Amended Complaint in Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES,



LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] were beneficiaries of inadvertent submissions of false claims to the State, subsequently discovered the falsity of the claims, and failed to disclose the false claims to the State within reasonable times after discovery of the false claims. On learning that Medi-Cal was paying inflated reimbursement amounts based upon the Defendants' falsely inflated reports of price and costs, and thereby paying false claims for the Defendants' drugs, the Defendants failed to disclose the false claims to the state within a reasonable time after discovery of the false claims. The Defendants' failure to disclose to the State, as required by Section 12651(a)(8), caused great financial loss to the State.

189. Defendants' conduct violated Government Code section 12651, subdivision (a)(8) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

# **FOURTH CAUSE OF ACTION**

# CALIFORNIA FALSE CLAIMS ACT, CAUSING PRESENTATION OF FALSE CLAIMS; ILLEGAL REMUNERATION

California Government Code section 12651, subdivision (a)(1)

- 190. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.
- 191. At all times relevant to this First Amended Complaint in Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME



CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knew that the prices charged to their customers for the specified pharmaceuticals were significantly reduced in amount from the prices and costs represented by the Defendants and upon which the Defendants knew Medi-Cal claims would be approved and paid. Accordingly, the Defendants have each knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from Medi-Cal to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the drugs named herein, and other drugs, for which the Defendants knew that payment would be made, in whole or in part, by Medi-Cal. Such financial inducement is specifically prohibited by California Welfare and Institutions Code section 14107.2. These paid or approved claims were grossly in excess of the amounts contemplated by law, resulting in great financial loss to the State.

- 192. The Defendants knew that Medi-Cal would not pay or approve claims for the drugs named herein, and other drugs, if it were disclosed to Medi-Cal that said claims were for amounts that included remuneration prohibited by California Welfare and Institutions Code section 14107.2.
- 193. The Defendants also knew that their customers, in presenting claims for the drugs named herein and other drugs to Medi-Cal, would not and did not disclose that the claim amounts included the remuneration prohibited by California Welfare and Institutions Code section 14107.2.
- 194. The Defendants' knowing [as defined in California Government Code section 12650, subdivision (b)(2)] and willful actions in arranging for their customers to receive



remuneration prohibited by California Welfare and Institutions Code section 14107.2, in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, the claims for the drugs named herein, and other drugs, to be false claims and caused the claims to be presented to Medi-Cal for payment and approval in violation of California Government Code section 12651, subdivision (a)(1).

195. Defendants' conduct violated Government Code section 12651, subdivision (a)(1) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

## FIFTH CAUSE OF ACTION

# CALIFORNIA FALSE CLAIMS ACT, CAUSING FALSE RECORDS OR STATEMENTS TO BE MADE OR USED TO GET FALSE CLAIMS PAID OR APPROVED BY CALIFORNIA; ILLEGAL REMUNERATION California Government Code section 12651, subdivision (a)(2)

- 196. The State and Qui Tam Plaintiff re-allege and incorporate by reference all of the previous allegations.
- 197. At all times relevant to this First Amended Complaint in Intervention, Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.;



ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a GENSIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, knew that the prices charged to their customers for the drugs named herein, and other drugs, were significantly reduced in amount from the prices and costs represented by the Defendants and upon which the Defendants knew Medi-Cal claims would be approved and paid. Accordingly, the Defendants have each knowingly [as defined in California Government Code section 12650, subdivision (b)(2)] offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from Medi-Cal to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the drugs named herein, and other drugs, for which the Defendants knew that payment would be made, in whole or in part, by Medi-Cal. Such financial inducement is specifically prohibited by California Welfare and Institutions Code section 14107.2. These paid or approved claims were grossly in excess of the amounts contemplated by law, resulting in great financial loss to the State.

- 198. The Defendants knew that Medi-Cal would not pay or approve claims for the drugs named herein, and other drugs, if it were disclosed to Medi-Cal that said claims were for amounts that included remuneration prohibited by California Welfare and Institutions Code section 14107.2.
- 199. The Defendants also knew that their customers, in presenting claims for the drugs named herein, and other drugs, to Medi-Cal, would not and did not disclose that the claim amounts included the remuneration prohibited by California Welfare and Institutions Code section 14107.2.
- 200. The Defendants' knowing [as defined in California Government Code section 12650, subdivision (b)(2)] and willful actions in arranging for their customers to receive remuneration prohibited by California Welfare and Institutions Code section 14107.2, in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused false records or



statements to be made and used to get false claims paid or approved by the State for the drugs named herein, and other drugs. The Defendants' actions herein caused said false records or statements to be made and used as prohibited by California Government Code section 12651, subdivision (a)(2).

201. Defendants' conduct violated Government Code section 12651, subdivision (a)(2) as set forth in this Count, and was a substantial factor in causing the State to sustain damages in an amount according to proof pursuant to California Government Code section 12651, subdivision (a).

#### IX.

# JURY DEMAND

202. The State and Qui Tam Plaintiff respectfully request a trial by jury as to all issues so triable.

# X.

# **PRAYER FOR RELIEF**

WHEREFORE, the State and the Qui Tam Plaintiff demand:

1. That judgment be entered in their favor and against Defendants ABBOTT LABORATORIES, INC.; AMGEN, INC.; ARMOUR PHARMACEUTICAL CO.; AVENTIS BEHRING, L.L.C.; AVENTIS PHARMACEUTICALS, INC.; B. BRAUN MEDICAL, INC.; B. BRAUN OF AMERICA, INC.; BAXTER HEALTHCARE CORP.; BEDFORD LABORATORIES; BEN VENUE LABORATORIES, INC.; BOEHRINGER INGELHEIM CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS INC.; BRISTOL-MYERS SQUIBB COMPANY a/k/a BRISTOL-MYERS ONCOLOGY DIVISION/HIV PRODUCTS; C.H. BOEHRINGER SOHN GRUNDSTUCKSVERWALTUNG GMBH & CO. KG; DEY, INC.; DEY, L.P.; EMD, INC.; GENEVA PHARMACEUTICALS INC.; GENSIA INC.; GENSIA SICOR, INC.; GLAXO WELLCOME INC. f/k/a BURROUGHS WELLCOME CO.; GLAXOSMITHKLINE PLC; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORP.; LIPHA, S.A.; McGAW, INC.; MERCK KGaA; MYLAN LABORATORIES, INC.; MYLAN PHARMACEUTICALS, INC.; NOVARTIS AG; PHARMA INVESTMENT, LTD.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHERING-PLOUGH CORP.; SICOR, INC. f/k/a



GENSIA PHARMACEUTICALS, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; WARRICK PHARMACEUTICALS CORP.; Z.L.B. BEHRING, with judgment to be entered against said Defendants, and each of them, for the amount of damages to Medi-Cal arising from claims for their specified prescription drugs and all other drugs as to which said Defendants engaged in substantially similar misconduct:

- (a) On the First Cause of Action (California False Claims Act; Causing Presentation of False Claims to California) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:
  - (i) Triple the amount of the State's damages;
  - (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
  - (iii) Recovery of costs, attorneys' fees and expenses;
  - (iv) Such other and further relief as the Court deems just and proper.
- (b) On the Second Cause of Action (California False Claims Act; Causing False Records or Statements To Be Made or Used To Get False Claims Paid or Approved By California) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:
  - (i) Triple the amount of the State's damages;
  - (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
  - (iii) Recovery of costs, attorneys' fees and expenses;
  - (iv) Such other and further relief as the Court deems just and proper.
- (c) On the Third Cause of Action (California False Claims Act; Beneficiaries of Inadvertent Submissions of False Claims to California, Subsequently Discover the Falsity of the Claims, and Fail to Disclose the False Claims to California Within Reasonable Time after Discovery of the False Claims) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:
  - (i) Triple the amount of the State's damages;



- (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
- (iii) Recovery of costs, attorneys' fees and expenses;
- (iv) Such other and further relief as the Court deems just and proper.
- (d) On the Fourth Cause of Action (California False Claims Act; Causing Presentation of False Claims; Illegal Remuneration) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:
  - (i) Triple the amount of the State's damages;
  - (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
  - (iii) Recovery of costs, attorneys' fees and expenses;
  - (iv) Such other and further relief as the Court deems just and proper.
- (e) On the Fifth Cause of Action (Causing False Records or Statements to Be Made or Used to Get False Claims Paid or Approved by California; Illegal Remuneration) damages as provided by California Government Code section 12651, subdivision (a) in the amount of:
  - (i) Triple the amount of the State's damages;
  - (ii) Civil penalties of Ten Thousand Dollars (\$10,000.00) for each false claim;
  - (iii) Recovery of costs, attorneys' fees and expenses;
  - (iv) Such other and further relief as the Court deems just and proper.
- 2. Further, the Qui Tam Plaintiff, on its behalf, requests that it receive such maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the State, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. The Qui Tam Plaintiff requests that its percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action.

Dated: August 24, 2005

BILL LOCKYER, Attorney General of the State of California



THOMAS A. TEMMERMAN, Senior Assistant Attorney General (Ret.)

**BRIAN FRANKEL** Supervising Deputy Attorney General

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On Behalf of the Qui Tam Plaintiff

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Attorneys for the Qui Tam Plaintiff



# CERTIFICATE OF SERVICE

I, BRIAN V. FRANKEL, hereby certify that on August 24, 2005, I caused a true and correct copy of the foregoing, FIRST AMENDED COMPLAINT IN INTERVENTION FOR MONEY DAMAGES AND CIVIL PENALTIES FOR VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT, WITH EXHIBITS A THROUGH R (all Exhibits except L are redacted), to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to Verilaw Technologies for posting and notification to all parties.

Dated: August 24, 2005

BRIAN V. FRANKEL

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